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Trial Day 11
Volume 2 of 2
December 11, 1997

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

GLAXO WELLCOME INC., et al.

Plaintiffs

v.

PHARMADYNE CORPORATION, et al.)

Defendants

Civil Docket No. AMD-96-455
And
Civil Docket No. AMD-96-1853
(Consolidated)

Baltimore, Maryland
December 11, 1997
2:40 p.m.

The above-entitled matter continued on for trial before
The Honorable Andre M. Davis.

A P P E A R A N C E S

On behalf of the Plaintiffs:

Stephen Judlowe, Esquire
John Henry Lewin, Jr., Esquire
Brian P. Murphy, Esquire
Robert G. Gibbons, Esquire
Regina Ambery, Esquire
Jason Lief, Esquire

On behalf of the Defendants:

James Rubin, Esquire
Alan H. Bernstein, Esquire
Robert S. Silver, Esquire
John M. Seeberger, Esquire
Deborah K. Besche, Esquire

Reported by: Betty Lou Walls, RPR

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I N D E X

WITNESS:

DIRECT

VOIR
DIRE

CROSS

REDIRECT

RECROSS

John Hempenstall

4241

4262

4340

4341

4343

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1 through this, the presence of ethanol does overall appear to
2 enhance stability but the effect is not large.

3 Q You gathered from her memorandum that it was her
4 conclusion that pursuing a patent for, for the ethanol patent
5 was a debatable proposition?

6 A That is what she said in this memorandum, yes.

7 Q Was there anything else in the last paragraph of her
8 memorandum that you thought was significant at all?

9 A Well, I think there is a comment at the bottom which
10 says that the analyst can see no chemical reason why ethanol
11 should enhance stability. So clearly our analysts had no
12 understanding as to what ethanol was doing, if anything.

13 Q All right. Now, did there come a time when a Michael
14 Atkinson made a request of you?

15 A Yes. Around about March 1990 Mike Atkinson got in
16 contact with me.

17 Q Who was Mike Atkinson?

18 A He works in the patent group at Glaxo Wellcome. I
19 think he is patent advisor.

20 Q What did he ask you to do?

21 A He asked me to write a declaration in support of the
22 '249 patent, which is the Zantac Syrup patent with ethanol.

23 Q When he made that request of you what did you do?

24 A Well, my first reaction was to find out what data we
25 had, so I went to the stability testing group, which is an

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1 independent group at Ware, and asked to see what programs
2 were on and then I decided to ensure -- well, the stability
3 testing group keeps data from the stability programs in two
4 ways, or did at that time. The raw data was kept as a paper
5 record, and I think you saw that yesterday; all those files,
6 that's the raw data. They also had an electronic version as
7 well called W STAB.

8 Q What does the W stand for?

9 A For the Ware facility as opposed to G, which is
10 Greenford. STAB is an electronic database. The electronic
11 version was typed in by secretaries who took the raw data and
12 typed it in. It wasn't a validated data set. I made sure
13 the electronic version matched the raw data set. So I
14 validated that myself.

15 Q If you look at the next exhibit in your folder,
16 Defendants' Exhibit 16, this purports to be an interoffice
17 memorandum dated March 16, 1990 from you to David Robinson.
18 Did you issue that memorandum?

19 A Yes, I did.

20 Q I take it this was your statistical department to
21 perform a statistical study on the data that appeared in the
22 W STAB?

23 A That's correct. What happened was I wanted --
24 obviously having collected the data from the stability group,
25 it needed to be properly dealt with it to look at it in a

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1 proper statistical way. So I contacted David Robinson, who
2 was head of the statistics group, to carry out the analysis
3 for me.

4 Q The first sentence of the fourth paragraph in the
5 memorandum states: The data available is quite extensive but
6 is equivocal. What did you mean by the word equivocal in
7 your memorandum?

8 A When I collected all the raw data together I glanced
9 through it and it was clear that some of the information was
10 quite close. That is the reference I meant.

11 Q What was your purpose in pointing out this to Mr.
12 Robinson in connection with the statistical study?

13 A That it was equivocal?

14 Q Yes.

15 A To make sure he did a proper study and we could
16 actually find out if there was an effect due to ethanol
17 stabilizing the Zantac Syrup.

18 Q Did you get a report from the statistical department
19 thereafter?

20 A I did. There were two people who worked for David
21 Robinson at that time, one was Gillian Amphlett and the other
22 was Nadeem Elahi. Nadeem reported to Gillian and Gillian
23 reported to Dave. I received a report on the statistical
24 analysis of the data from Nadeem Elahi.

25 Q If you look at what has been marked as Plaintiffs'

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1 Exhibit 247 and Defendants' Exhibit 34, which is the next
2 exhibit in your folder, that is the report that you received
3 from Dr. Elahi or Mr. Elahi sometime after May 15?

4 A That's correct, yes.

5 Q What did you do with the report when you got it?

6 A The first thing I did was to have a cursory glance at
7 it and then send a copy to my then superiors, Dr. Peter Rue
8 and Mike Atkinson, because I noticed they weren't copied on
9 the report.

10 Q We'll come back to Exhibit 247 in a minute, but look at
11 the next exhibit in your folder, Defendants' Exhibit 84. Is
12 this a copy of the transmittal memorandum of May 23 that you
13 sent to Mr. Atkinson with a copy to your supervisor, Dr. Rue?

14 A Yes, it is. In it there is a cover note to that report
15 and it says the statisticians have completed their analysis
16 was Zantac Syrup data. Copy of report enclosed, which was
17 the Nadeem Elahi report. It appears that ethanol either
18 increases stability or has no effect at all.

19 Q Did you further go on to say that you thought the
20 analysis supported the patent claim but only marginally?

21 A I did.

22 Q What did you mean by that message?

23 A Well, having had a cursory glance at it, it was clear
24 that some of the data was quite close, in particular the UK
25 data. That was my reference there to being marginal.

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